

S/N 10/089,431

PATENTREMARKS

Favorable review is requested in view of the above amendments and following remarks. The revisions to claims 1, 11 and 21 are supported, for example, at page 7, line 30 - page 8, line 3. Claims 3-5, 7, 13-15, 17, 22-24 and 26 have been canceled without prejudice. Claims 1, 2, 6, 8-12, 16, 18-21, 25, 27 and 28 are pending in the application. Features similar or identical to those added to the independent claims already had been included in the dependent claims. In addition, it is submitted that the prior art issue raised in the current office action could have been made in the first office action, and therefore, entry of this Amendment as a matter of right is requested.

Claims 1-20 have been rejected as obvious over Deurer, Godbey and Fukiage. Applicants respectfully traverse this rejection.

The rejection relies on Godbey as teaching various penetration enhancers. See page 3 of the Office Action. However, while the reference discloses a large number of potentially useful substances that include isopropyl myristate (Col. 6, line 37-38) and polyoxyethylene oleyl ether (Col. 6, lines 49-50), nothing in the reference remotely suggests that these materials should be chosen out of the long list and used together as required by independent claims 1, 11 and 21.

The present specification demonstrates the unexpected advantages that are achieved with the present invention. See Tables 3-5 at pages 16-17 of the specification. In particular, note the results of samples P2-P5 versus those of samples P7-P10. Samples P2-P5 report results with

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various combinations of isopropyl myristate (IPM) and polyoxyethylene oleyl ether (EAO9995). Samples 7 and 8 report results with EAO9995 alone, while samples 9-10 report results with IPM alone. The results are tabulated below for ease of reference.

Table A: Accumulative Drug amounts transferred: Use of a single enhancer	
Transdermal Patch No.	Accumulative amount transferred [$\mu\text{g}/\text{cm}^2$]
P8 (20% EAO9995)	64.74
P7 (10% EAO9995)	42.83
P10 (20% IPM)	7.66
P9 (10% IPM)	4.14

Table B: Accumulative Drug amounts transferred: Use of combined enhancers		
Transdermal Patch No.	Accumulative amount transferred [$\mu\text{g}/\text{cm}^2$]	
	Found	Expected based on Combined Single Enhancer Effects
P5 (20% EAO9905+20% IPM)	316.72	72.40 (P8+P10)
P4 (20% EAO9905+10% IPM)	166.61	68.88 (P8+P9)
P3 (10% EAO9905+20% IPM)	77.53	50.49 (P7+P10)
P2 (10% EAO9905+10% IPM)	59.92	46.97 (P7+P9)

It can be seen that the combination of the two enhancers improves the transfer of the active agent significantly even compared to the combined effects of each enhancer individually. Nothing in the prior art suggests any reason to expect that such results should be achieved, and the rejection should be withdrawn.

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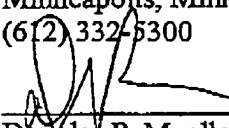
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In view of the above, favorable reconsideration in the form of a Notice of Allowance is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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